

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval
Under
Simplified Acquisition Procedures (SAP)
Simplified Acquisition Threshold (\$3K to \$150K)
For Restricting Competition under FAR 13.106-1(b)(1) "Single Source"**

1. Contracting Activity:

Department of Veterans Affairs, Network Contracting Office (NCO) 20, for the, Anchorage VAMC (463)

2. Nature of the Action Being Processed:

This action is for obtaining emergency medications for a cancer Veteran patient which is required immediately of Imbruvica (Ibrutinib) 140mg 90 count bottle

3. Description of Supplies or Services Required to Meet the Agency's Needs:

The purchase of this chemo medication supports the VA's mission of providing the latest FDA approved medication to support the life and care of our Veterans whom have given all to our country. This medication is required ASAP, and will need to order 1 bottle at a time as needed for the Veteran's refills through 09-30-2014

4. Statutory Authority Permitting Restriction in Competition:

The statutory authority for restricting competition under SAP, or Single Sourcing, for acquisitions under \$150,000 or Simplified Acquisition Threshold (SAT) is **41 U.S.C. 253(c), as implemented by FAR 13.106-1(b)(1)**. The specific reason for restricting competition is an urgent and compelling need to obtain this medication for the health and welfare for a Veteran patient. Delays in obtaining this medication may have an adverse and negative affect on the patient's care. This justification is where in accordance with FAR 6.001(a), acquisitions conducted under FAR 13 for SAP are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2, IAW the VHA SOP for Other Than Full And Open Competition dated 3-22-2011.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

The manufacturer of this specialty drug is allowing only 1 vendor to sell their product. This is a standard in the specialty pharmaceutical industry in order for FDA guidelines to be met and/or to keep pertinent records of sales to pharmacies.

6. Description of Efforts Made to Ensure that Offers are Solicited from As Many Potential Sources as Deemed Practicable IAW FAR 13.104:

As detailed in item 5, above.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable – IAW FAR 13.106-3:

The anticipated price to the Government is \$ 6,107.36/90 ct bottle x 6= \$36,644.16 there is only 1 vendor allowed by the manufacturer to sell this specialty medication, Ibrutinib at the Federal Ceiling Price. The VA NAC Pharmacy Benefits Services Management Services gave directions on how to purchase on 2/20/14 ✓

8. Description of the Market Research Conducted and the Results, or Statement of Reasons Market Research was not Conducted (FAR 10):

Market research was conducted as detailed in item 5 and 7, above

9. Any Other Facts Supporting the Restriction of Competition:

No other facts that have not been previously noted.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

No other sources were sought, beyond those already noted.

11. Statement of Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making Subsequent Acquisitions for the Supplies or Services Required:

No other actions are planned due to the nature of the commodity.

12. Requirements Certification - IAW FAR 6.303-2(c):

I certify that the requirement outlined in this justification is a bonafide need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Benjamin Jensen
Chief of Pharmacy Service AK VAMC



Date

13. Approvals IAW VHA SOP 3.22.11:

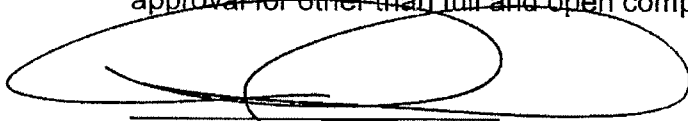
- a. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



John MacBride
Contracting Officer
NCO 20 Supply Team "1"

Date 20 MAR 14

- b. **NCM/PCM/DESIGNEE:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval for other than full and open competition.



John Kopp
Contract Manager
NCO 20 Supply Team "1" - Team Manager

Date 20 MAR 14